

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Remkes et al.
SERIAL NO. : 10/543,174
FILED : July 22, 2005
FOR : METHOD AND DEVICE FOR SUPPLY OF A DIALYSIS UNIT
WITH DIALYSIS FLUID
GROUP ART UNIT : 1777
EXAMINER : Bass, Dirk
CONFIRMATION NO: 7919

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Commissioner for Patents
P.O. Box 1450
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REPLY BRIEF UNDER 37 CFR 41.41

Sir:

In response to the Examiner's Answer of April 26, 2011, for which a response is due by June 27, 2011 (since June 26, 2011 falls on a Sunday), Applicant submits this Reply Brief in the above-referenced application. A Notice of Appeal was previously filed on November 11, 2010 and an Appeal Brief was previously filed on February 11, 2011. The Office is hereby authorized to charge any fees necessary for consideration of this paper to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

STATUS OF CLAIMS

Claims 16-40 are currently pending. Claims 1-15 were previously cancelled. Claims 16-22, 31-34 and 36-38 are currently withdrawn as directed to a non-elected invention.

Claims 23-30, 35, 39 and 40 stand finally rejected and are subject to appeal.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 24 is indefinite under 35 USC 112, 2nd paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Whether claims 23-30, 35, 39 and 40 are anticipated under 35 U.S.C. 102(b) by U.S. Patent 5,744,027 to Connell et al. (“Connell”).

ARGUMENT

Appellants herein incorporate all the arguments previously presented in the Appeal Brief filed February 11, 2011.

Rejection Under 35 USC §102(b) Over US Patent 5,744,027 to Connell et al. (“Connell”)

Independent Claims 23 and 26 and Dependent Claims 24, 25, 27-30, 35, 39 and 40

A. Means-Plus-Function Language under 35 U.S.C. § 112, 6th paragraph

According to MPEP 2181, “[a] claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis: (A) the claim limitations must use the phrase “means for” or “step for;” (B) the “means for” or “step for” must be modified by functional language; and (C) the phrase “means for” or “step for” must not be modified by sufficient structure, material, or acts for achieving the specified function.” MPEP 2181. The Examiner states that “applicant uses ‘means plus function’ language for the recitation of a ‘means for setting a dialysing fluid flow rate.’” (Examiner’s Answer, page 6).

Applicants submit that the following claim language meets the 3 prong analysis and thus invokes means-plus-function under 35 U.S.C. § 112, paragraph 6. Independent claim 23 recites “a means for setting a dialysing fluid flow rate Qd_b during a dialysis treatment *such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate.*” Independent claim 26 recites “a means for setting a dialysing fluid flow rate Qd_v over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate in the at least one receiving unit at the end of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , *such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate.*” The Examiner does not appear to dispute this. However, Applicants submit that the Examiner does not properly interpret this means-plus-function language.

B. Intended Use as Opposed to Means-Plus-Function Language

The Examiner does not allege that Connell performs the claimed function, but rather simply ignores the specific claimed function. Applicants submit that the authority upon which the Examiner relies is inappropriate for means-plus-function claim language. The Examiner states that “[w]hile applicants argue that Connell does not disclose the specific function of the ‘means for setting a dialysing fluid flow rate,’ the examiner considers such limitations to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a ***structural difference*** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (MPEP 2111.02).” (Examiner’s Answer, pages 6-7). MPEP Section 2111.02 is entitled “Effect of the Preamble” and is directed to the preamble of a claim. The passage that Examiner appears to paraphrase is under the heading of “Preamble Statement Reciting Purpose or Intended Use” and states, “[d]uring examination, statements *in the preamble* reciting the purpose or intended use of the claimed limitation must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art.” MPEP 2111.02, II. (emphasis added). Since the claim limitations in question are not in the claim preamble, this MPEP section is inapplicable to the claim interpretation of these means-plus-function claim limitations, and the Examiner’s reliance on this MPEP section is misplaced.

The Examiner also relies upon MPEP 2114, stating that “a claim containing a ‘recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus’ if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).” (Examiner’s Answer, page 7). However, MPEP Section 2114 is entitled “Apparatus and Article Claims – Functional Language” and the beginning of this section states, “[f]or a discussion of case law which provides guidance in interpreting the functional portion of means-plus-function limitations see MPEP §2181 - §2186.” Thus, it is clear that MPEP section 2114 does not apply to means-plus-function limitations. Rather, means-plus-function limitations must be interpreted as outlined in MPEP 2182, which states that “the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim.” MPEP § 2182 (emphasis added).

C. The Reference Must Perform an Identical Function to Read on a Means-Plus-Function Claim Limitation

The Federal Circuit held “because no distinction is made in paragraph six between prosecution in the PTO and enforcement in the courts, or between validity and infringement, we hold that paragraph six applies regardless of the context in which the interpretation of means-plus-function language arises, i.e., whether as part of a patentability determination in the PTO or as part of a validity or infringement determination in a court.” *In re Donaldson Company, Inc.*, 16 F.3d 1189, 1193 (Fed. Cir. 1994). Thus, the following decisions relating to means-plus-function limitations in the infringement/validity context apply to the instant patentability determination before the USPTO.

“Literal infringement of a claim with a means-plus-function clause requires that the accused device perform a function identical to that identified in the means clause.” *Ishida Co., Ltd. v. Taylor*, 221 F.3d 1310, 1316 (Fed. Cir. 2000) (emphasis added). “Such a limitation cannot be met by an element in a reference that performs a different function.” *RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 1445 n. 5 (Fed. Cir. 1984) (emphasis added). “To determine whether a claim limitation is met literally, where expressed as a means for performing a stated function, the court must compare the accused structure *with the disclosed structure*, and must find equivalent structure as well as *identity* of claimed *function* for that structure.” *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) *overruled (on other grounds) by* *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993). (emphasis in original). “If the required function is not performed *exactly* in the accused device,” there is no literal infringement. *Id.* If an accused device “does not perform a function identical to that of [the] claim...[then] although it has equivalent structure, the [accused device] does not literally infringe the claim.” *WMS Gaming Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1352 (Fed. Cir. 1999). Although not binding precedent, in *Ex Parte Powers*, the Board stated that “[f]or a means-plus-function limitation to read on a device, the device must employ means identical or equivalent to the corresponding structures, materials, or acts described in the specification and must also perform the identical function as specified in the limitation.” *Ex Parte Powers*, 2003 Pat. App. LEXIS 52 (BPAI 2003) (emphasis added).

Furthermore, the prior art reference must perform the *complete identical function* as recited in the claims (as argued previously). However, the Examiner is ignoring half of the claim language by interpreting the phrase “a means for setting a dialysing fluid flow rate Q_{d_b} during a dialysis treatment *such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate*” of claim 23 and the phrase “a means for setting a dialysing fluid flow rate Q_{d_v} over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate in the at least one receiving unit at the end of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , *such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate*” of claim 26 as simply a “means for setting a dialysing fluid flow rate.” (Examiner’s Answer, page 4).

In *WMS Gaming*, the Federal Circuit interpreted the claim limitation of a “means for assigning a plurality of numbers representing said angular positions of said reel, said plurality of numbers exceeding said predetermined number of radial positions such that some rotational positions are represented by a plurality of numbers.” *WMS Gaming Inc.*, 184 F.3d at 1347. The Court gave weight to the entire function recited in the claim, determining “[t]he claimed function of the ‘means for assigning’ limitation is ‘assigning a plurality of numbers representing said angular positions of said reel, said plurality of numbers exceeding said predetermined number of radial positions such that some rotational positions are represented by a plurality of numbers.’” *Id.*

D. Connell Does Not Perform An Identical Function

Applicants submit that Connell does not perform the claimed function and that the Examiner does not allege that Connell does. Connell does not disclose performing the claimed functions of: setting a dialysing fluid flow rate Q_{d_b} during a dialysis treatment *such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate*; or setting a dialysing fluid flow rate Q_{d_v} over the remaining dialysis treatment period T_{B2} which depends upon a volume of the at least one dialysing fluid concentrate in the at least one receiving unit at the end

of the pre-set time interval of the dialysis treatment T_{B1} , the first pre-set volumetric ratio, and the remaining dialysis treatment period T_{B2} , *such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate.*

Connell describes a ultrafiltration/proportioning UF/PROP controller 516 that controls the systems associated with ultrafiltration and dialysate preparation, including flow control (column 15, line 65-column 16, line 15). The controller 516 controls the dialysate flow rate (column 17, line 21). However, Connell does not disclose that the controller 516 adjusts the flow rate *such that at the end of the pre-set treatment period T_B , the at least one receiving unit is either empty or contains a pre-set residual volume of the at least one dialysing fluid concentrate* as recited in claim 23. Additionally, Connell does not disclose that the controller 516 adjusts the flow rate *such that at the end of the dialysis treatment period, the at least one receiving unit is either empty or contains the pre-set residual volume of the at least one dialysing fluid concentrate* as recited in claim 26.

The Examiner relies upon a theoretical function, arguing that “the controller of Connell is capable of performing the function recited in the claims.” (Examiner’s Answer, page 7). However, the fact is that Connell’s device does not perform the claimed function. The prior art reference must **perform** the claimed function, not simply be **capable of** performing the function. In *Pennwalt Corp. v. Durand-Wayland, Inc.*, the Federal Circuit affirmed the finding of no literal infringement, stating that “[w]e need not, and do not, determine whether the district court correctly found no equivalency in structure [under 112, 6th] because the district court also found that the accused devices, in any event, did not perform the same functions specified in the claims.” *Pennwalt*, 833 F.2d at 934 (emphasis added). The Federal Circuit also affirmed the finding of no infringement under the doctrine of equivalents, stating that “[t]he claim limitations...require the performance of certain specified functions. Theoretically, a microprocessor **could be programmed** to perform those functions. However, the district court found that the microprocessor in the accused devices **was not so programmed**.” *Id.* at 935 (emphasis added). The Court further stated that “the accused machine simply *does not do* what [the expert] explains ‘could’ be done...While a microprocessor theoretically could be programmed to perform that function, the evidence led the court to a finding that the [accused] machines performed a *substantially different* function from that which each of the claims

requires.” *Id.* at 938. Applicants submit that this doctrine of equivalents analysis is applicable in the context of literal infringement (or a patentability determination), insofar as a device that does not infringe under the doctrine of equivalents also could not infringe under the more stringent test of literal infringement. Thus, Connell must not merely be capable of performing an identical function, but must actually perform an identical function to that claimed.

E. Connell Does Not Disclose a Structure That is the Same as or Equivalent to the Corresponding Structure

According to the MPEP, “if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.” MPEP § 2182 (emphasis added). As explained above, Connell does not teach identity of function. Furthermore, Connell does not disclose the same structure or an equivalent structure to the corresponding structure for the means disclosed in the instant specification. The Examiner states that “Connell discloses a controller which is responsive to user input for controlling the dialysing fluid flow rate (C17/L20-49).” (Examiner’s Answer, page 7).

With respect to the first embodiment, described in claim 23, the instant specification describes a control and calculating unit 24 that “calculates the dialysis fluid flow rate Q_{d_b} which is required to ensure that there is no residual volume of concentrate in the canister at the end of the treatment time; to do this it uses the quantity M_{i1} of the concentrate remaining in the canister at the beginning of the effective dialysis treatment after the test at first time point t_1 , the pre-set duration of the treatment time T_B and the pre-set volumetric relationship V_1 of the acid concentrate K1 and water W.” (page 8, lines 24-29). The quantity M_{i1} , which is used in determining the fluid flow rate Q_{d_b} , is disclosed as being determined the following way (see page 7, line 20 - page 8, line 11). Before dialysis treatment commences, quantities of the following variables are entered into the input unit 25: T_B , V_1 , V_2 , M_1 , M_2 . The control and calculating unit 24 communicates with input unit 25 by a data lead 39. The control and calculating unit 24 sets flow rates of proportioning pumps 17, 18 and 20 such that the concentrates K1 and K2 are mixed with water in the pre-set volumetric ratio. Then the control

and calculating unit 24 calculates the quantity of concentrate which was used during the time interval T_{test} from the pre-set flow rates of proportioning pumps 17, 18. The control and calculating unit 24 then calculates the quantity of concentrate remaining at the time the dialysis treatment commences from the difference between the M1 and M2 and the quantity of concentrate that was used during the time interval T_{test} , which is M_{t1} . The second embodiment, described in claim 26, “differs from the first example only in that the control and calculating unit 24 of the supply equipment lays down a different program sequence.” (page 9, lines 29-30).

Applicants submit that the “program sequence” described in the specification is part of the corresponding structure in the instant application. With respect to interpreting a means-plus-function limitation, the Federal Circuit determined that “the structure disclosed in the specification to perform the claimed function was ‘an algorithm executed by a computer.’” *WMS Gaming Inc.*, 184 F.3d at 1348. Based on this claim interpretation, the Court thus found that “[t]he two structures are not identical because the microprocessor disclosed in the Telnaes patent [at issue] is programmed differently from the microprocessor disclosed in the Durham patent.” *Id.* at 1350. Thus, although Connell’s controller 516 controls the dialysate flow rate, it does not describe a structure that is the same or equivalent to the corresponding structure in the instant specification.

CONCLUSION

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's decision rejecting claims 23-30, 35, 39 and 40 and direct the Examiner to pass the case to issue.

Respectfully submitted,

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